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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Marine Fisheries Service

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-XXXX; FRL-XXXX-X]

[EPA RIN: 2070-AD72]

[FWS RIN: XXXX-XXXX]

[NMFS RIN: 0648-AQ69]

Endangered Species and Pesticide Regulation

AGENCIES: Fish and Wildlife Service (FWS), Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration (NOAA), Commerce; and Environmental Protection Agency (EPA).

ACTION: Advance Notice of Proposed Rulemaking

SUMMARY: This Advance Notice of Proposed Rulemaking (ANPR) announces the intention of the Fish and Wildlife Service (FWS), a bureau of the Department of the Interior, and the National Marine Fisheries Service (NMFS), an Agency of the National Oceanic and Atmospheric Administration (NOAA), [jointly referred to as "the Services"], in cooperation with the U. S. Environmental Protection Agency (EPA), to conduct rulemaking to promulgate "counterpart regulations" under the Endangered Species Act (ESA). Specifically, this notice focuses on regulations and policies affecting the process for consultation between EPA and the Services regarding EPA actions in its pesticide regulatory program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and does not address processes among the Services and any other office within the EPA. Throughout this rulemaking process, the Services and EPA will work with the United States Department of Agriculture (USDA) to implement the purposes of the ESA and to effectuate the intent of the Congress that ESA compliance for EPA's FIFRA program be designed to "minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators." Public Law 100-478, October 7, 1988. This ANPR also seeks public

comment on possible approaches to changing the current regulations, policies, and practices of the EPA and Services to better integrate the FIFRA and ESA processes and to improve the efficiency and effectiveness of consultations on pesticide actions to enhance protection of species that are Federally listed or proposed as threatened or endangered and their proposed or designated critical habitat. The agencies are specifically requesting comments that focus on developing solutions to the extremely complex issues surrounding these consultations. In addition, this ANPR seeks comment on ways to improve public involvement and understanding of these processes and the decisions that result from them.

DATES: Comments, identified by docket ID number OPP-2002-**XXXX**, must be received on or before [insert date **45** *days after date of publication in the* **Federal Register**].

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:

For FWS: Richard E. Sayers, Jr., Endangered Species Program, U. S. Fish and Wildlife Service, ARL SQ42, 1849 C St., NW, Washington, DC 20240; telephone number: (703) 358-2106; fax number: (703) 358-1735; e-mail address: Rick_Sayers@fws.gov

For NOAA: Laurie Allen, Office of Protected Resources,, National Marine Fisheries Service; National Oceanic and Atmospheric Administration; 1315 East-West Highway, Room 13821, Silver Spring, MD ; telephone number: (301) 713-2322, fax number: (301) 713-0376; e-mail address: Laurie.Allen@noaa.gov

For EPA: Arthur-Jean Williams, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5239; fax number: (703) 308-3259; e-mail address: williams.arty@epa.gov

SUPPLEMENTARY INFORMATION:

This Notice is organized into four Units. Unit I contains “General Information” about the applicability of this Notice, how to obtain additional information, how to submit comments in response to the request for comments, and certain other related matters. Unit II provides background information on the pesticide regulatory program and the process by which Federal agencies consult or confer with the FWS and NMFS to insure appropriate protection of Federally listed and proposed, threatened and endangered species (“listed species”) and their proposed and designated critical habitat (“critical habitat”). It also explains why EPA and the Services are considering changing the current approach to consultation for EPA’s pesticide regulatory program and the goals of any future changes. Unit III of the Notice identifies specific aspects of the existing consultation process followed by EPA and the Services and seeks public comment on how these aspects might be modified to improve the consultation process

for EPA's pesticide regulatory program. Finally, Unit IV discusses regulatory assessment requirements.

I. General Information

While this ANPR is being issued jointly by EPA and the Services, because EPA has an electronic docket system that allows distribution of materials more easily to interested persons, EPA has agreed to take responsibility for all of the administrative duties related to publication of this document, including the creation of a public docket, receipt of public comments, and other related matters. EPA will share all comments it receives with the Services, and all three agencies will work together to compile and analyze public comments and on any future steps.

A. Does this Action Apply to Me?

This action is directed to the public in general and may be of particular interest to persons who manufacture, sell or use pesticides or who are part of a State or Tribe engaged in the regulation of pesticide products and to groups interested in environmental regulation. The Agency and the Services have not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-**XXXX**. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information

claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA and the Services are not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying

or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2002-**XXXX**. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP-2002-**XXXX**. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC, 20460-0001, Attention: Docket ID Number OPP-2002-**XXXX**.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA., Attention: Docket ID Number OPP-2002-**XXXX**. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.A.1.

D. How Should I Submit CBI to EPA?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set

forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Background

A. What Action are the Agencies Taking?

The Fish and Wildlife Service (FWS) of the Department of the Interior and the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA), together with the Environmental Protection Agency (EPA), announce their intent to conduct rulemaking to make changes in the way that EPA consults with FWS and NMFS (jointly referred to as "the Services") under the Endangered Species Act (ESA) on regulatory actions involving pesticides, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The Services and EPA are issuing this Advance Notice of Proposed Rulemaking (ANPR), in consultation with the United States Department of Agriculture (USDA), to solicit public comment on a range of possible changes that are intended to better integrate the consultation process under section 7 of the ESA with the process for pesticide regulatory actions taken by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) , and to improve the efficiency and effectiveness of consultation on pesticide actions.. Some of the possible changes would require modification of the Services' existing consultation regulations in 50 CFR Part 402; a rule modifying the consultation

regulations for a specific Federal agency is called a "counterpart regulation." See 50 CFR 402.04. Other possible changes in the current approach to consultations between EPA and the Services could be accomplished without rulemaking, for example through a Memorandum of Understanding or changes in policies and practices at EPA or the Services.

EPA and the Services are currently engaged in a number of separate, but related activities relative to EPA's responsibilities under the ESA, in addition to the publication of this ANPR. First, under ESA section 7(a)(1), EPA and the Services are engaged in an ongoing Proactive Conservation Review. This review of EPA's Endangered Species Protection Program (ESPP) is intended to clarify for the involved Federal agencies EPA's approach to risk assessment, criteria that indicate a listed species may be at risk, and the requirements imposed on EPA by the ESA regulations governing consultation. The review will also identify areas or issues relative to risk assessment, criteria, and consultations that may require modification to enhance the effectiveness and efficiency of consultation among EPA and the Services. While this review is conducted under ESA section 7(a)(1), the outcomes of the review will likely be used to help focus discussions on technical and science policy issues that need to be addressed to carry out responsibilities under ESA section 7(a)(2) more effectively and efficiently. Second, on December 2, 2002, EPA published a Notice in the Federal Register describing and requesting comments on implementation of its ESPP. 67 FR 71549. The goal of the ESPP is to carry out EPA's responsibilities under FIFRA in compliance with the ESA, while at the same time not placing unnecessary burden on agriculture and other pesticide users.

Although this ANPR contemplates significant revisions to the Services' ESA regulations as they relate to EPA's pesticide regulatory programs under FIFRA, EPA will continue to address its ESA section 7(a)(2) obligations regarding pesticide actions under existing Service rules until such time as the changes contemplated by this ANPR are finalized. While EPA and the Services believe these revisions can greatly improve the efficiency and effectiveness of the consultation process, all three agencies believe that the work they will be doing under the existing regulations during this interim period will ensure that endangered species are protected to the fullest extent of the law.

EPA and the Services believe it is also important that the public and pesticide registrants and users understand that EPA has significant authority under FIFRA to protect endangered species and their habitats from potentially harmful exposure to pesticides, and that FIFRA provides EPA the exclusive statutory authority for modifying a pesticide registration. Accordingly, when regulatory action is determined to be appropriate to protect listed species or their habitat, EPA will use the authority and procedures set forth in FIFRA to undertake such action.

B. What are the Agencies' Authorities for Taking this Action?

This ANPR is issued under the authority of section 7 of the Endangered Species Act (ESA), as amended, 16 USC secs. 1531 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 USC secs. 136 et seq. EPA's statutory authority and programs for regulating pesticides are discussed in section C of this Unit, while section D., below, describes the applicable provisions of the ESA and

implementing regulations.

C. FIFRA and Pesticide Regulation

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is the primary statute under which EPA regulates the use of pesticides in the United States. 7 USC secs. 136 et seq. FIFRA defines a "pesticide" as ". . . any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest . . . ." FIFRA sec. 2(u). When a pesticide is sold or distributed, it is generally referred to as a "pesticide product." Pesticides contain both "active ingredients" and "inert ingredients." An "active ingredient" is ". . . an ingredient which will prevent, destroy, repel, or mitigate any pest . . . ." FIFRA sec. 2(a). Ingredients which are not active are referred to as "inert ingredients" or "other ingredients." Under FIFRA, an "inert ingredient" is defined as "an ingredient which is not active." FIFRA sec. 2(m). EPA uses the term, "formulation," to refer to the particular combination of active and inert ingredients in a pesticide product. A pesticide "use" refers to the particular combination of circumstances under which a pesticide product may be applied, such as the rate, timing, method, and site of application.

The Statutory Framework for Regulation of New Pesticide Products. FIFRA generally prohibits the sale or distribution of a pesticide product unless it has first been "registered" by EPA. FIFRA sec. 12(a)(1)(A). EPA issues a license, referred to as a "registration," for each specific pesticide product allowed to be marketed; the registration approves sale of a product with a specific formulation, in a specific type of package, and with specific product labeling for a specific use. Each product is evaluated on a case-by-case basis.

FIFRA requires a person seeking to register a pesticide to demonstrate that the proposed product meets the statutory standard. EPA may approve the unconditional registration of a pesticide product only if the Agency determines, among other things, that use of the pesticide would not cause "unreasonable adverse effects on the environment." FIFRA sec. 3(c)(5). The statute defines "unreasonable adverse effects on the environment" to include "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. . . ." FIFRA sec. 2(bb).

When EPA registers a pesticide, it approves among other things a specific set of labeling for the product which contains directions for and restrictions on use of the product. Labeling includes any written or graphic material attached to the product container, i.e., the label, as well as other material accompanying the product or referenced on the label. FIFRA sec. 2(p). FIFRA makes it unlawful for any person "to use any registered pesticide in a manner inconsistent with its labeling." FIFRA sec. 12(a)(2)(G). Thus, directions and restrictions appearing on, or referenced in, a pesticide product label become enforceable Federal requirements. Under FIFRA, most States have primary responsibility for enforcement against pesticide misuse. See FIFRA sec. 26.

While most regulatory decisions allowing entry of new pesticide products into the marketplace are made by EPA in its registration program, there are two other programs

that can authorize the use of new pesticides. Under section 18 of FIFRA, EPA may allow the use of an unregistered pesticide product by a State or Federal agency when necessary to address an emergency situation. Under EPA's regulations, a petition for an exemption must establish that "emergency conditions" – defined as "an urgent, non-routine situation that requires the use of a pesticide . . ." – exist and that no effective, currently registered pesticide or non-pesticidal pest control method is available. 40 CFR 166.4(d). The emergency exemption regulations provide that EPA will not approve a request unless EPA determines, among other things, the use of the pesticide product will not cause unreasonable adverse effects on the environment. 40 CFR 166.25(b). In addition, under certain limited circumstances, States may approve a new use of a currently registered pesticide product to meet a "special local need." FIFRA sec. 24(c). EPA's regulations limit States' exercise of this authority only to the approval of products that contain active ingredients that are present in a currently approved pesticide product and give EPA broad authority to disapprove products intended for uses that are not closely related to existing uses. See 40 CFR 162.152. States must notify EPA when they exercise this authority and a State's registration shall not be effective for more than 90 days if disapproved by EPA within that period. FIFRA sec. 24(c)(2).

The Statutory Framework for Regulation of Existing Pesticide Products. In addition to a registration program for new pesticide products, EPA conducts a "reregistration" program. Reregistration focuses on currently registered pesticides and involves a systematic reexamination of the scientific data to determine whether the pesticides continue to meet contemporary scientific and regulatory standards. See FIFRA sec. 4. Among other things, EPA assesses whether there are adequate data to determine if the statutory standard is met. FIFRA gives EPA authority to require registrants to provide data if EPA "determines [the] additional data are required to maintain in effect an existing registration of a pesticide." FIFRA sec. 3(c)(2)(B). (Imposition of such additional data requirements is subject to the provisions of the Paperwork Reduction Act, 44 USC secs. 3501 - 3520.) In the past, EPA has used this authority to require registrants to conduct studies that would provide additional data needed for the evaluation of potential hazards of and exposures to pesticide products. EPA uses such data to assess pesticide risks and to determine whether changes in the terms and conditions of registration would be appropriate. In many cases, EPA's reregistration review has concluded that additional risk mitigation measures were necessary to reduce potential harm to non-target plants and wildlife populations. Many registrants voluntarily have amended their products' registrations to implement these risk mitigation measures. If, however, registrants do not adopt needed risk mitigation, EPA may impose the requirements through cancellation or suspension proceedings, conducted pursuant to FIFRA sec. 6 and 40 CFR Part 164.

EPA may issue a notice of intent to cancel the registration of a pesticide if it appears that the continued use of the pesticide "generally causes unreasonable adverse effects on the environment." FIFRA sec. 6(b). Thus, the standard for approving a pesticide's entry into the marketplace and the standard for retaining a pesticide on the market is based on a determination relative to "no unreasonable adverse effects" Because cancellation proceedings can be lengthy, FIFRA also contains provisions allowing EPA to "suspend" the registration and use of a pesticide, prior to the completion of a cancellation process, if use of the pesticide poses an

"imminent hazard." FIFRA sec. 6(c). FIFRA defines an "imminent hazard" as "a situation which exists when the continued use of a pesticide during the time required for [a] cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened under [the Endangered Species Act]." FIFRA sec. 2(l).

Ecological Risk Assessment. In deciding whether a pesticide product meets the statutory standards for registration or reregistration, EPA considers, among other things, the potential risks to non-target wildlife and plant species posed by use of the pesticide product. EPA's evaluation of such environmental risks follows the principles contained in its Guidelines for Ecological Risk Assessment. (EPA 1998). In 1986, EPA developed detailed guidance for the review and analysis of potential environmental risks from use of pesticide products. See Standard Evaluation Procedures (SEP) for Ecological Risk Assessment (EPA 1986). Since 1986 EPA has made many additions and refinements to the basic approach outlined in the SEP. All of EPA's risk assessment methods have included methodology for an assessment of potential risks to listed species. Refer to the ESPP Federal Register Notice (67 FR 71549) for a more detailed description of how EPA assesses the risk to listed species.

EPA requires both new and existing pesticides to be supported by extensive information about the potential ecological risks of the pesticide product. Data requirements appear in EPA regulations at 40 CFR Part 158. Studies conducted to generate data for EPA are subject to Good Laboratory Practice requirements that are designed to ensure that the results are reliable and of high quality. See 40 CFR Part 160. EPA's scientists carefully review all data submissions and independently evaluate the potential risks of each pesticide. In situations raising novel or challenging scientific issues, EPA generally seeks outside peer review of its scientific assessments.

The Agency requires extensive toxicity and environmental fate data and uses this information, together with field reports of adverse effects on wildlife caused by pesticides and other relevant information, to evaluate the potential hazards to non-target species, including threatened and endangered species, for a pesticide intended for outdoor use. To assess potential hazard to non-target species, EPA requires a basic set of laboratory toxicity studies on an active ingredient using multiple surrogate species of birds, fish, aquatic invertebrates, non-target insects, and plants. In situations where additional, scientifically valid, toxicity data related to effects on wildlife and aquatic organisms are available, EPA will consider them in establishing the toxicity endpoint for risk assessment. It is EPA's policy to conduct risk assessments using the toxicity endpoint from the most sensitive species tested. EPA also requires data from a series of laboratory and field studies of the environmental fate of both the active ingredients in a pesticide product and typical formulations containing the active ingredient. These studies provide data on both the parent active ingredient, as well as its environmental degradates . The Agency combines these data, along with information about how the pesticide product is intended to be used, to develop an estimate of the potential concentrations of residues of the active ingredient and significant environmental degradates in the environment (the Estimated Environmental Concentration or EEC). In order to avoid underestimating risk, EPA makes assumptions designed not to understate potential exposure.

When assessing risks to listed species, EPA evaluates data and risks in a tiered fashion. The Agency compares its toxicity assessment of an active ingredient with the EEC. If the comparison demonstrates that the EEC is well below the amount of active ingredient that would be expected to cause harm to a particular species or critical habitat, EPA would conclude that the use of pesticide products containing that active ingredient would have "no effect" on listed species. Most of EPA's focus is on the potential risks from exposure to the active ingredient and its significant environmental degradates. EPA also has information, both on the other ingredients in pesticide products and on the formulations themselves, with which to assess the potential for increased risk. This ingredient- and formulation-specific information and many years of reviewing pesticide products support a general conclusion that inert ingredients in formulations usually do not make more than a negligible contribution to the overall environmental risks posed by a pesticide product formulation. If the initial comparison and subsequent refined assessments indicate that EPA's best estimate of the EEC for the active ingredient and / or significant environmental degradates could have toxic effects on a listed species, then EPA may require the pesticide sponsor to supply additional laboratory and/or field data in order to refine the risk assessment, require changes in the allowable use of the pesticide product that are sufficient to mitigate any potential risk, or determine it necessary to request initiation of consultation with the Services to obtain a Biological Opinion on actions that might be taken relative to reducing risk. Higher tier toxicity data may include studies on the effects of a pesticide on other wildlife species and plants or studies of longer durations of exposure. The Agency may occasionally require higher tier studies to be conducted in the field under simulated or actual use conditions. EPA may also require additional information to improve its estimate of potential exposure. Possible risk mitigation measures include changes in the manner or timing of pesticide applications, the rate or frequency of applications, or geographical restrictions on use.

D. The Endangered Species Act and Federal Agency Consultations with the Services

Section 7 of the ESA imposes obligations upon all Federal agencies whose actions may adversely impact listed species. Of particular relevance to this ANPR, section 7(a)(2) directs all Federal agencies, in consultation with and with the assistance of the Secretaries of the Interior and Commerce (delegated to the Services), to insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of habitat of such species that has been designated as critical ("critical habitat"). 16 USC 1536(a)(2). In meeting this requirement, each agency is required to use the "best scientific and commercial data available." 16 USC 1536(a)(2).

The Services adopted joint regulations set forth at 50 CFR Part 402, which include procedural requirements. These regulatory provisions require action agencies to consult with the Services on all Federal actions that "may affect" a listed species or critical habitat. Consultation may be concluded "informally" if the action agency, with written concurrence from the Services, determines that the Federal action under consideration is "not likely to adversely affect" a listed species or critical habitat. 50 CFR 402.14(b)(1). "Formal" consultation is required on actions that are likely to adversely affect a listed species or critical habitat and when the Services disagree with an action agency's determination that the action is "not likely to adversely affect" the

species or its critical habitat. During formal consultation, focus is on whether the proposed Federal action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. 50 CFR 402.14(h).

By regulation, the consultation process reviews a variety of potential "effects" on listed species and habitat, including direct, indirect, and cumulative effects. "Direct effects" are those effects that will immediately flow from the proposed action. "Indirect effects" are those that will be caused by the proposed action, will occur later in time, but are still reasonably certain to occur. "Cumulative effects" are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the area affected by the proposed action. 50 CFR 402.02. Additionally, examination includes the effects of "interrelated" and "interdependent" actions. For a detailed explanation of these terms, please refer to the Consultation Handbook jointly published by NMFS and FWS, which further elaborates on the procedures followed by the Services when conducting section 7 consultations.
http://endangered.fws.gov/consultations/s7hndbk/s7hndbk.htm

During formal consultation, focus is upon whether the proposed Federal action is likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. 50 CFR 402.14(h).

At the conclusion of formal consultation, the Services will issue a "biological opinion" that details the effects of the action on the listed species or critical habitat, and whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. 16 USC 1536(b)(3)(A). A "jeopardy" biological opinion must include reasonable and prudent alternatives, if any are available. Where jeopardy or adverse modification of critical habitat does not exist, the Services must issue an incidental take statement that specifies reasonable and prudent measures necessary to minimize incidental impact. 16 USC 1536(b)(4). When the terms and conditions of the incidental take statement are followed, all incidental takings that occur are not subject to liability. 16 USC 1536(o).

Service regulations implementing section 7 also authorize the promulgation of counterpart regulations, that establish alternate consultation procedures for a particular Federal agency. 50 CFR 402.04. Authority to promulgate counterpart regulations acknowledges that in certain instances, the section 7 consultation process can benefit from procedures that differ from the traditional consultation process established by the Services. This ANPR contemplates such regulations.

E. EPA's and the Services' Goals for this Notice

The Services and EPA are seeking ways to better integrate the FIFRA pesticide registration and ESA section 7 consultation processes thereby making the Section 7 consultation on pesticides more effective and efficient. Additionally, EPA and the Services are seeking to improve public involvement in and understanding of the consultation process on FIFRA actions. In order to meet these goals, the Services and EPA, in consultation with USDA, will likely propose counterpart regulations governing

section 7 consultation for EPA's regulatory actions, as well as any changes to the FIFRA policies and practices, which may be necessary. In addition, EPA and the Services are considering other procedural modifications to the consultation process for pesticide regulation.

In 1988, Congress addressed the relationship between the ESA and EPA's pesticide labeling program. Public Law 100-478, October 7, 1988, amended the ESA and required EPA to conduct a study, and to provide Congress with a report of the results, on ways to implement EPA's endangered species pesticide labeling program in a manner that both complies with the ESA and allows people to continue production of agricultural food and fiber commodities. Thus, the clear sense of Congress is that EPA should fulfill its obligation to conserve listed species, while at the same time considering the needs of agriculture and other pesticide users. Accordingly, EPA and the Services are working with USDA in this process.

EPA and the Services share the same overall goal–to improve their capacity to provide needed protection for listed species and their critical habitat in an expedited manner that is not unnecessarily burdensome for pesticide users. The Services and EPA believe that procedures and policies that result in better integration of the ESA consultation process with pesticide regulatory programs–both registration and reregistration–should lead to more efficient production of scientifically sound assessments of risks to listed species and critical habitat. That, in turn, should benefit both the listed species and those affected by EPA's pesticide regulatory programs. Improving the process, including shortening the time frames for ESA review of currently registered pesticide products, would enable EPA to more efficiently implement risk mitigation measures to prevent jeopardy to listed species and to avoid adversely modifying critical habitat. Moreover, many of the applications submitted for registration of pesticide products containing new active ingredients involve pesticide formulations that could have less impacts than the currently registered products with which they would compete. Thus, any improvements in the efficiency and effectiveness of the ESA review process could similarly benefit listed species, as well as more broadly provide benefits for human health and the environment. Finally, given the importance of pesticide use for such essential purposes as production of food and fiber and disease prevention, EPA and the Services believe that improved integration of the FIFRA registration/reregistration and section 7(a)(2) consultation processes , under new counterpart regulations, modification to the FIFRA processes, or through other mechanisms will be achieved in a way that avoids unnecessary burdens on pesticide users.

In developing a process for conducting future ESA consultations on FIFRA pesticide regulatory actions, the agencies believe it is important to recognize that EPA possesses significant resources and expertise in the field of ecological risk assessment relative to pesticides, while the Services possess the technical and regulatory expertise necessary for consistent administration of the ESA. Under FIFRA EPA makes decisions to allow new or continued use of a pesticide only after carefully examining extensive data on the potential risks that use of a pesticide may pose to non-target wildlife species. In addition, EPA's pesticide regulatory program may require companies to conduct studies needed for a risk assessment. As a result, EPA generally has significant scientific information available with which to evaluate the hazards a

pesticide may pose to non-target wildlife. Further, to perform its responsibilities under FIFRA, EPA must maintain a sizeable staff of well-qualified scientists with many years of combined experience in assessing ecological risks. Finally, EPA has performed pioneering work in certain areas of ecological risk assessment, such as the development of exposure models and probabilistic risk assessment techniques.

In addition to its strong scientific databases and its expertise in the field of ecological risk assessment, EPA's decisions have certain relatively unique characteristics. Pesticide products typically include multiple uses, and can potentially be used in many different parts of the country. Thus, in evaluating a pesticide, EPA considers different locations where the product may be used and whether wildlife or plant species may be affected by such use. This broad scope of review contrasts with actions by Federal agencies that have a narrower geographical scope. In addition, the number of pesticide decisions is also a factor potentially affecting the section 7 consultation process. In a typical year, EPA will make hundreds of decisions regarding pesticide registration, some involving very extensive risk assessments, while others require more limited reviews. For example, in fiscal year 2002, EPA registered 26 new pesticide active ingredients; approved the addition of 720 new uses of previously registered active ingredients on close to 1500 different crops; and completed more than 4700 more minor registration actions. EPA also completed reregistration assessments on 36 previously registered active ingredients, and processed over 500 emergency exemption requests in FY 2002. Numbers of actions in most of these categories have risen since FY 2000. The combination of the number and variety of pesticide regulatory decisions EPA makes each year, together with the possible use of pesticide products on multiple sites located in different parts of the country, means that the potential number of consultations about the effects of EPA actions could be far greater than result from any other single Federal regulatory program.

The implementation of a number of the changes discussed in Unit III would require modification of the existing consultation regulations and FIFRA procedures. We are interested in public comment on changes to the current approach to consultation that could be put into effect without rule-making, such as through interagency agreements.

III. Request for Comment

This Unit of the ANPR invites public comment on a number of ways in which the current regulations, policies, and practices of the Services and EPA regarding ESA consultations about decisions in the pesticide regulatory program could be modified. Section A of this Unit focuses on possible approaches to identifying types of actions that would not require case-by-case consultation between EPA and the Services. Section B asks for comments on possible changes to the existing framework, while retaining the basic approach of requiring consultation whenever EPA determines that use of a pesticide "may affect" protected species. Section C invites public comment on certain other aspects of the operational relationship between EPA and the Services. The agencies note that the specific approaches described below do not exhaust all of the possible changes that might improve the effectiveness and efficiency of the consultation process. Thus, the agencies invite the public to include comments on

other ways to modify the regulations, policies and practices of EPA, FWS or NMFS to achieve our mutual goals.

Finally, the agencies emphasize that they have made no decisions with respect to pursuing any specific modification discussed below. The agencies will consider public comments about a particular proposed change in light of the following factors, among others: the consistency of the approach with the requirements of ESA and FIFRA; the scientific soundness of the approach; and the impact of the approach on government resources, pesticide users, and others.

A. The Scope of EPA's Consultations on FIFRA Actions Under the ESA

1. Programmatic Consultation.

Under existing Service regulations at 50 CFR Part 402, the Services and federal agencies can engage in consultations that address major national programs. There is potential to use this authority to develop a "programmatic" approach to consultation on the pesticide registration program. In regulating pesticides under FIFRA, EPA does not develop overall pesticide registration and reregistration programs as, for instance, the Forest Service might develop a forest plan; rather, EPA makes decisions about new and existing pesticide uses on a case-by-case basis, subject to the standards of FIFRA described above. While these decisions are made on a case-by-case basis, in many circumstances these individual registration decisions share common elements. For example, EPA receives hundreds of applications per year for so called "me-too" pesticide products that are identical or nearly identical to currently registered pesticides. In addition, some classes of pesticides that aren't identical may nonetheless share common exposure or toxicological profiles. Even where pesticides may not share common characteristics, there may be approaches to risk assessment and risk management that are appropriate for identifying and addressing risk concerns to listed species across broad classes of pesticides.

Thus, in circumstances where such commonalities exist, it may be possible for EPA to satisfy some or all of its ESA section 7(a)(2) consultation obligations for individual registration actions by completing what could be described as "programmatic" consultations affecting numerous registration and reregistration actions simultaneously. In addition, even where such programmatic consultations are not sufficient to complete the consultation process for certain individual actions, they may serve to streamline the consultation process on such actions through the standardization of risk assessment methodologies and alternatives for species protections.

While the Services' current section 7 regulations provide authority for agencies to consult on a group of related actions in this fashion, there may be benefits to using counterpart regulations to establish criteria that would delineate the circumstances under which EPA would be expected to consult with the Services and the circumstances where consultation would not be necessary. Such regulations could identify those practices that EPA would follow to identify and delineate potential adverse effects on listed species and their habitat, as well as the data standards for such evaluations. Such regulations could lead to more efficient use of resources by

both the Services and EPA, while at the same time providing the public with an opportunity to participate more fully in the process of protecting listed species.

EPA and the Services welcome comments on this approach and specifically request that commenters consider the following questions in developing their submissions:

- What are the administrative and programmatic advantages and disadvantages of this approach?
- What elements of EPA's pesticide program are particularly amenable to programmatic consultation?
- To what extent, if any, could or should this approach change the consultation process for specific regulatory actions under FIFRA?
- To what extent would it be appropriate to change any of EPA's data requirements, risk assessment methods, or criteria for evaluating potential risks to listed species in connection with such a "programmatic" consultation?
- What are the advantages or disadvantages to implementing this approach through rulemaking?
- What are the advantages or disadvantages to implementing this approach under the Services' existing consultation regulations?
- What would be the appropriate method for addressing issues associated with incidental take under this approach?

2. Changes to the Informal Consultation Process

As described in Unit II. D above, the ESA requires Federal agencies to consult with the Services in meeting their section 7(a)(2) obligations to insure that agency actions are not likely to jeopardize listed species or destroy or adversely modify any critical habitat of such species. The current consultation regulations at 50 CFR Part 402 provide that in circumstances where a Federal agency determines that its actions "may effect" a listed species or critical habitat it must engage in consultation with the Services. In circumstances where an agency concludes that an action will have "no effect" on listed species or critical habitat, no further consultation is required, and the Federal agency, under such circumstances, has satisfied its section 7(a)(2) obligations regarding such action.

In those circumstances where a Federal agency cannot conclude that its actions will have "no effect" on listed species or critical habitat, but can conclude that its actions are "not likely to adversely affect" listed species or critical habitat, Service regulations provide that if the relevant Service concurs in writing on that determination the agency need not engage in further, (i.e., formal) consultation with the Service. 50 CFR 402.13. The concurrence approach, in these situations, serves as a Service

opinion or interpretation that the agency has satisfied its section 7(a)(2) obligations regarding such actions.

Under these circumstances the Services have determined, by regulation, that formal consultation is unnecessary for individual agency actions in order for Federal agencies to satisfy their section 7(a)(2) obligations. While this regulatory regime currently applies to, and is generally appropriate for, a wide variety of Federal agency actions, there may be circumstances where the mission and expertise of a particular agency, or a particular office within an agency, may lend itself to the development of alternative or additional informal processes. EPA's regulation of pesticides may be one such instance. As explained in Unit II. C, one of EPA's core functions in the regulation of pesticides under FIFRA is the development of extensive ecological risk assessments, including an evaluation of the effects that pesticide use may have on various plant and animal taxa. As a result, EPA may possess sufficient information and analytical expertise to make informed determinations as to whether a pesticide is "not likely to adversely affect" a listed species or critical habitat. For this reason, EPA and the Services think it is appropriate to consider whether there is a need for either further consultation or Service concurrence in those situations where EPA determines that use of a pesticide is "not likely to adversely affect" listed species or critical habitat.

This ANPR therefore seeks comment on whether to pursue, through counterpart regulations or other mechanisms, either of the two following potential approaches to conducting consultation on pesticide regulatory actions (1) If EPA determines that a pesticide is not likely to adversely affect listed species or critical habitat, no further consultation would be required; or (2) Where EPA determines that a pesticide is not likely to adversely affect listed species or critical habitat, EPA would continue to consult with the Services but EPA would not need to obtain the written concurrence of the Services to satisfy its section 7(a)(2) obligations.

EPA and the Services welcome comments on these alternate approaches and specifically request that commenters consider the following questions in developing their submissions:

- The administrative and programmatic advantages and disadvantages of these approaches.
- In connection with such regulations, what, if any, criteria should the Services establish which, if met, would support one or both of the approaches.
- Whether in connection with such regulations it would be appropriate or necessary to change any of EPA's data requirements, risk assessment methods, or criteria for evaluating potential risks to protected species.
- Whether there are additional changes to the informal consultation process that may be warranted.

3. Focused review by the Services during consultation

The immediately preceding alternative explores amendments to the circumstances under which informal consultation would be necessary. This alternative considers potential approaches to formal consultation that would focus review provided by the Services once formal consultation had been initiated. It is predicated on the assumption that in the development of this rulemaking, EPA's practices and policies would be reviewed and, where necessary revised to ensure that the data and analyses EPA obtains and uses provides the best available information on the effects to threatened and endangered species. As discussed earlier, EPA has extensive information available with which to assess and mitigate potential risks to listed species and their critical habitat and EPA has developed considerable expertise in these areas. Thus in the case of pesticide regulatory actions, the Services would rely on EPA's assessment of effects more heavily than many other types of federal actions.

When formal consultation is necessary, an approach would be to provide for a more focused review of EPA pesticide submissions by the services. This approach would provide for a rebuttable presumption regarding the adequacy of the effects analysis in an EPA request to initiate formal consultation. There are many potential standards that could be applied to determine whether the effects analysis would be deemed adequate (see 50 CFR 402.14(c)). This ANPR identifies three:

- whether EPA had considered the most current and best available scientific, commercial, and technical information on listed species and their habitat and that the determinations were not arbitrary and capricious;
- whether there was clear and convincing information warranting a different conclusion as to the effects of the proposed registration;
- whether there is substantial evidence to support EPAs effects determinations.

Whatever standard is incorporated into a counterpart regulation, once the adequacy of the effects analysis is established, the Services would rely on EPA's determinations of effects in completing the formal consultation process.

EPA and the Services are seeking comments on this approach and specifically request that commenters consider some of the following questions in developing their submissions:

- What are the administrative and programmatic advantages and disadvantages of this overall approach

- What are the administrative and programmatic advantages and disadvantages of specific provisions.

- What are other possible appropriate evidentiary or procedural provisions.

- Should the Services establish criteria which, if met, would justify such an approach?

- Would it be appropriate to change any of EPA's data requirements, risk assessment methods, or criteria for evaluating potential risks to protected

species?

B. Modifications of the Existing Framework Under FIFRA and the ESA to Increase the Effectiveness, Efficiency, and Flexibility of the Existing Interagency Process

1. Modification of EPA's Approach to Assessing Potential Risk to Protected Species

EPA routinely receives and evaluates extensive scientific information on the potential hazards of and exposure to pesticide active ingredients as part of its registration and reregistration processes. Unit II. C contains an overview of this evaluation process and EPA's ESPP Notice describes the risk assessment process in more detail. Please comment on whether there is a need to modify the current assessment process for evaluating the potential risks to protected species, including whether there should be any changes to EPA's data requirements, assessment algorithms, or criteria for judging whether the use of a pesticide poses a potential risk to listed species.

2. Scope of a consultation

EPA's registration and reregistration decisions typically involve one or more pesticide products containing a specific active ingredient. A single pesticide product is generally registered for use on multiple crop and / or non-crop sites and may be applied on any approved site throughout the United States. Thus, a single registration encompasses multiple separate decisions by EPA. The ESA currently requires a Federal agency to insure that its "actions" do not jeopardize protected species or adversely modify critical habitat. The Services' regulations state that "[a]ny request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given area or a segment of a comprehensive plan." 50 CFR 402.14(c). Thus, EPA and the Services have discretion to determine the scope of the regulatory action subject to both formal and informal consultations. Please comment on the advantages and disadvantages of using counterpart regulations or other mechanisms to give EPA and the Services more flexibility to define the scope of EPA's consultation with respect to a specific regulatory action. For example, please comment on whether it would be appropriate to have the ability to define EPA's proposed action in a way that would limit a consultation on a registration decision to: a particular geographical area, a particular ingredient in a pesticide formulation, or a particular use of a pesticide product.

3. The contents of a consultation package

The ESA requires that "each agency shall use the best scientific and commercial data available." ESA sec. 7(a)(2). The Services' consultation regulations specify that a written request to initiate formal consultation shall contain:

"(1) a description of the action to be considered;

(2) A description of the specific area that may be affected by the action;

(3) A description of any listed species or critical habitat that may be affected by the action;

(4) A description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects;
(5) Relevant reports, including any environmental impact statements, environmental assessments, or biological assessments prepared; and
(6) Any other relevant available information on the action, the affected listed species, or critical habitat."

50 CFR 402.14(c). The Services' regulations define "cumulative effects" to mean "those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation." 50 CFR 402.02. The consultation regulations do not establish any requirements with respect to the content of a request for an informal consultation.

Please comment on:

- The meaning of the statutory phrase, "best scientific and commercial data available," with respect to the type of information EPA should be required to include in a review package.

- The advantages and disadvantages of issuing counterpart regulations to modify the existing requirements in 50 CFR 402.14(c).

- Whether the same requirements apply to review packages submitted for informal consultation as for formal consultation or whether informal consultation packages should be subject to any regulatory requirements since they are informal?

- Given that most EPA actions involve multiple pesticide uses that may from regional to national in scope, what is the most effective and efficient way to address the concept of "cumulative effects" as defined under the Services regulations at 50 CFR 402.02.

4. <u>The timeframe for completing formal and informal consultation on pesticide regulatory actions</u>

The ESA sets a goal of 135 days for concluding a formal consultation, but also contains provisions that allow the action agency and the Services to agree, in certain circumstances, to extend the deadline for completing the consultation. See ESA sec. 7(b). Neither the ESA nor the Services' consultation regulations establish a timeframe for completion of informal consultations.

Please comment on the advantages and disadvantages of:

- establishing specific timeframes for concluding formal consultations on pesticide regulatory decisions, including the possibility of a shorter timeframe and what action by EPA should trigger the start of a time period for formal consultation..
- establishing specific timeframes for concluding informal consultations on pesticide regulatory actions and what action by EPA should trigger the

start of a time period for informal consultation

- defining specific circumstances under which the timeframes should be extended and what those circumstances might be.

5. Identify and establish procedures for dealing with an "emergency" for purposes of emergency consultation and other expedited review

The Services' consultation regulations contain provisions allowing consultation to be conducted in an expedited manner in "emergency circumstances." 50 CFR 402.05. This provision applies to "situations involving acts of God, disasters, casualties, national defense or security emergencies, etc." The regulations state that expedited consultation may be conducted in any manner consistent with the ESA, and that formal consultations "shall be initiated as soon as practicable after the emergency is under control." Under FIFRA, EPA may issue exemptions to States or Federal agencies to allow the use of an unregistered pesticide when "emergency conditions exist which require such exemption." FIFRA sec. 18.

Please comment on whether these and other types of regulatory actions taken by EPA's pesticide programs should be considered "emergencies" that would justify conducting any required ESA consultation in an expedited manner. For example, if consultation with the Services were required, should emergency consultation provisions apply to:

- petitions for emergency exemptions under FIFRA sec. 18
- notifications to EPA of state issuance of "special local needs" registrations under FIFRA sec. 24(c);
- other circumstances giving rise to a need for expedited review?
- are there any circumstances where no review by the Services is appropriate, for example, when the action is taken to address a public health emergency as described in 40 CFR Part 166, under FIFRA?

6. Clarify the role of the Services

As discussed above in Unit II. D, the ESA and existing consultation regulations describe the role that the Services play in providing advice and opinions on the impact of agency actions on protected species and their critical habitat.

What are the advantages and disadvantages of using counterpart regulations or other mechanisms to establish additional responsibilities for the Services, for example, by specifying that the Services should assist EPA in developing the information base for consultation or by specifying the types of information that the Services should provide to EPA? What other responsibilities, if any, should the Services assume? Should counterpart regulations (or some other mechanism) establish a process that a Service follows to ensure that, when different parts of its organization issues Biological Opinions on the same pesticide and / or species, its Biological Opinions are consistent? If so, how should that process operate?

7. Clarify the term "applicant" and the participation afforded to applicants.

The current consultation regulations define the term, "applicant," as a person

"who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action." 50 CFR 402.02. The regulations provide that an applicant shall have an opportunity to submit information for formal consultations, join discussions with the Services on consultation issues, and comment upon request on a draft of Biological Opinions before it is issued in final form by the Service. 50 CFR 402.14.

Should the role outlined in current regulations for an "applicant" be retained in counterpart regulations. If so, how should it be applied with respect to pesticide regulatory actions and what procedural rights should such an "applicant" have? At what points in the consultation process should the general public have an opportunity to participate?

8. Clarify and improve the role of States and Tribes and other potential non-Federal representatives

The current consultation regulations state that a Federal agency may designate a non-Federal representative to prepare biological evaluations and / or to conduct informal consultation with the Services. 50 CFR 402.08. While the regulations do not specify who may (or may not) act as a non-Federal representative, they do indicate that, in some circumstances, an "applicant" may be a non-Federal representative.

Please comment on the circumstances, if any, that pesticide companies could or should be designated as a non-Federal representative. In addition, please comment on whether, in view of the role that States and Tribes play in the enforcement of EPA regulatory decisions under FIFRA, States or Tribes could or should be designated as non-Federal representatives [Inconsistent with section 7(a)(2)]

Should any special or additional procedures be established to provide greater participation of States and Tribes in the consultation process, either as a non-Federal representative or in another capacity?

9. Fees

A substantial increase in the number or complexity of consultations between EPA and the Services will require a corresponding increase in agency resources.

Please comment on whether it would be appropriate to charge fees to offset the added expenditures that would be necessary to conduct such consultations. Who should pay such fees, and how should the amount of any fee be determined?

10. Process for elevating and resolving disagreements between EPA and the Services

Neither the ESA nor the current consultation regulations prescribe how an action agency and the Services will resolve disagreements arising under ESA. EPA and the Services, however, have addressed this issue with respect to consultations about two of EPA's regulatory programs involving water. See Memorandum of Agreement, 66 FR 11202 (February 22, 2001).

Please comment on the advantages and disadvantages to using counterpart regulations or some other mechanism to establish procedures for expedited resolution of disagreements between the Services and EPA.

C. Other Programmatic Aspects of the Consultation Process

EPA's ESPP Notice has invited public comment on the most appropriate approach to structure consultations about the potential impacts of pesticides on listed species. The ESPP Notice identified several possible approaches: consultation on a pesticide-by-pesticide basis, on a geographically defined site-by-site basis; on a crop-by-crop basis; or a species-by-species basis. See 67 FR 71,549 (December 2, 2002).

In addition to issues about the structure of consultations, EPA and the Services are interested in issues relating to establishing priorities for such consultations. In view of the scope of the pesticide regulatory program, EPA and the Services think the number of consultations that may be needed in the foreseeable future could involve substantial resources. Moreover, given the number of pesticides and their potentially widespread and overlapping uses, the agencies foresee that there could be a large degree of potentially redundant effort unless the consultation process is carefully managed to achieve the most efficient use of limited resources. The Services and EPA therefore invite comment on any additional approaches that might improve the overall consultation process. In particular, the agencies invite comments on the feasibility and usefulness of developing a comprehensive, priority-based schedule for completing any necessary consultations. If such a schedule would be appropriate, how should the Services and EPA determine which consultations should receive highest priority? What role, if any, should the public have in forming the priorities for consultation? How should any priority scheme for endangered species determinations relate to existing schedules for reregistration under FIFRA?

IV. Regulatory Assessment Requirements

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), it has been determined that this advance notice of proposed rulemaking is a "significant regulatory action" under section 3(f) of the Executive Order, because it raises "novel legal or policy issues arising out of legal mandates." The Agency therefore submitted this ANPR to OMB for the 10-day review period afforded under this Executive Order. Any changes made in response to OMB comments during that review have been documented in the public docket as required by the Executive Order.

Since this ANPR does not impose any requirements, and instead seeks comments and suggestions for the Agency to consider in developing a subsequent notice of proposed rulemaking, the various other review requirements that apply when an agency imposes requirements do not apply to this advance notice of proposed rulemaking.

As a part of your comments on this document, you may include any comments or information that you have regarding these requirements. In particular, any comments

or information that would facilitate the Agency's assessment of the potential impact of a procedural rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.). The Agency will consider such comments during the development of the notice of proposed rulemaking as it takes appropriate steps to address any applicable requirements.

List of Subjects in 50 CFR Part 402

Endangered species, environmental protection, pesticides

Dated:_____

_____

Assistant Secretary for Fish and Wildlife and Parks,
U. S. Department of the Interior

Dated:_____

_____

Assistant Administrator for Fisheries,
National Oceanic and Atmospheric Administration
U. S. Department of Commerce

Dated:_____

_____

Administrator
U. S. Environmental Protection Agency

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